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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/811,014 | 03/26/2004 | David G. Wild | CV0330 NP | 9570 |

26079 7590 08/04/2009

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| EXAMINER | |
|---|---|
| OSTRUP, CLINTON T | |
| ART UNIT | PAPER NUMBER |
| 3771 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 08/04/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/811,014 | WILD ET AL. | |
| | Examiner | Art Unit | |
| | CLINTON OSTRUP | 3771 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-3,5,7,8,10,11,14,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,8,10,11,14,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. This Office Action is in response to the amendment filed April 22, 2009. No claims have been amended, no claims were cancelled, and no claims were added in this amendment. Thus, claims 1-3, 5, 7, 8, 10, 11, 14, 19 and 20 are presently pending in this application.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5, 7-8, 10-11,14 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barak (6,494,852) in view of Taheri (4,624,244).

Barak discloses a compression device for the limb of a mobile patient (fig. 1) comprising: an inflatable sleeve 1 (fig.2) adapted to surround the limb; a conduit 4 attached to said sleeve for delivering fluid to said sleeve; and a portable, wearable controller 3 (fig. 1) or control unit 68 (col. 6, lines 63-67) attached to said conduit that generates and controls the flow of fluid in the device; wherein the sleeve includes a leg cuff and a foot cuff (fig. 2); the leg cuff has three cells on the lower sleeve including: a gaiter cell 2 adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell 2 adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell 2 adapted to wrap around the lower limb in the region

between the mid-calf cell and the knee (best seen in fig. 2), except that it does not explicitly disclose that the sleeve includes consists of a leg cuff and a foot cuff and the leg cuff consists of only three cells and each cell consisting of only one compartment..

However, Barak teaches that "the invention is also intended for use on any body limb such as a foot, a part of a leg" (col. 4, lines 14-15) and "the number of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35).

Taheri teaches a similar compression device having a sleeve with a leg cuff (27) and a foot cuff (11); the leg cuff consists of three cells: a gaiter cell (B) adapted to (partially) wrap around the lower limb in the region closest to the ankle, a mid-calf cell (C) adapted to (partially) wrap around the lower limb above the region occupied by the gaiter cell and an upper cell (D) adapted to (partially) wrap around the lower limb in the region between the mid-calf cell and the knee with each cell having only one compartment (bladders inside B, C, and D) for the treatment of diseased leg veins which result in venous hypertension. See: figures 1-3 & col. 1, lines 13-27.

Therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to limit the Barak device to include only a leg cuff and a foot cuff, as taught by Taheri, in order to obtain a device that could be used to treat the lower limb of a person having diseased leg veins.

Since Barak already teaches that "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), and Taheri suggest forming a lower leg treatment device, it would have been obvious to one having ordinary skill in the art at the time the invention was made to eliminate the cell of the thigh, to form a

lower leg treatment device. Moreover, since it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. In re Karlson, 136 USPQ 184.

Re claims 2-3, 5, 7, Barak discloses the controller comprises a microprocessor control system (control unit 68, col. 6, lines 63-67) and a pump (pump unit 60, col. 6, lines 22-33); wherein at least one pressure sensor 62/63 or pressure monitoring means (col. 6, lines 37-38) is associated with said sleeve ; wherein said sleeve is low profile and discrete (fig. 1); said leg and foot cuffs are anatomically shaped to provide compression on those parts of the leg or foot which have the greatest effect on blood flow (best seen in fig. 2).

Re claims 10-11 and 19, Barak discloses that the controller is battery operated (rechargeable battery pack 67, col. 6, lines 26-28); wherein each cell is monitored by a sensor 62/63 (col. 6, lines 37-38); and a method of preventing or treating edema or DVT (col. 2, lines 42-49) comprising applying a compression device of claim 1 to the limb of a mobile patient.

Re claims 8 and 20, Barak discloses the claimed inventions having all the features except for a sock interposed between the sleeve and the limb. Having a patient wear a sock, when using the device, would be obvious to a skilled artisan. A sock would prevent direct contact of the device with the patient's skin and would therefore prevent direct contamination of the user's skin, and/or the transfer of bodily fluids to, or from, the user to the device. Moreover, a sock would help prevent skin

irritation, skin shear and chaffing at the contact surface between the device and the skin of the limb during use.

Re claim 14, Barak discloses the claimed inventions having all the features except it is silent regarding the cells may be pressurized to the same or different predetermined pressures. However, Barak teaches (fig. 5) a pressure system 50 that has a range of pressure of 50-100 mmHg, and therefore it would have been obvious to one of ordinary skill in the art at the time of invention was made to operate the Bark's pressure system, such that the cells may be pressurized to the same or different predetermined pressures, for the purpose of providing a variety of compression therapy being applied on different body parts of the patient suitable to the patient's condition.

***Response to Arguments***

4. Applicant's arguments with respect to claims 1-3, 5, 7-8, 10-11, 14 and 19-20 have been considered but are not persuasive.

5. As previously discussed, applicant's argument that one of ordinary skill in the art would believe that it is essential to pressurize the thigh in order to obtain benefit from that device, has not been found convincing and the examiner respectfully disagrees.

There is no evidence disclosed in Barak et al. to teach that the device would not work without the thigh cuff. Furthermore, since Barak already teaches that "the number of cells in the sleeve can vary, according to the desired treatment" (col. 10, lines 34-35) and "various changes, omissions to the form and detail thereof may be made therein" (col. 10, lines 38-40), there appears to be no unobviousness for Barak to apply pressure only to the foot and leg, especially in view of the teaching of Taheri, which clearly

teaches a compression device having a sleeve consisted of a leg cuff (13) and a foot cuff (11) with the leg cuff having only three cells (B-D), which have a gaiter cell B adapted to wrap around the lower limb in the region closest to the ankle, a mid-calf cell C adapted to wrap around the lower limb above the region occupied by the gaiter cell and an upper cell D adapted to wrap around the lower limb in the region between the mid-calf cell with the cells each having only one compartment (bladders B-D) for treatment of diseased leg veins.

It is also well established that "The separation of elements, where removability would be desirable, is a design consideration within the skill of the art." *In re Dulberg*, 283 F.2d 522, 129 USPQ 348 (CCPA 1961).

In the instant case, it is clear that when a physician is treating a patient, they treat the part of the body in need of said treatment. Thus, if a physician was to treat a lower leg, it would be obvious to modify a leg treatment device to treat only the body part needing treatment. Since Barak discloses that "The control unit, which can be software based, controls the operation of the compressor and solenoid valves. The control unit can be programmed to achieve any desired inflating and deflating sequence and timing including delay intervals, in accordance with clinical application", a physician treating the lower leg could program the control unit to deflate and indefinitely delay inflating of the thigh portion of the device or merely modify the device to form a lower leg treatment device, taught by Taheri, to form a treatment device consisting of a leg and foot cuff.

Regarding applicant's submission that when Barak described "it is to be understood that the invention is also intended for use on any body limb such as an arm,

a foot, a part of a leg, arm or foot, and may be used on two or more limbs simultaneously" the 'part of a leg' is meant to encompass the entire leg absent "the knee, the ankle, or the upper thigh" is not taken well. A physician treats areas in need of treatment. Based on the teachings of the combined references, a skilled artisan would clearly recognize that Barak could be modified to treat a lower leg and foot without the need of the thigh region as specifically taught by Taheri. See: figure 1 of Taheri.

Regarding applicant's argument that Barak does not teach the number of cuffs can vary, this argument is not taken well because the rejection is based on the combination of references and Taheri teaches a lower leg cuff and a foot cuff.

Applicant's arguments against the references individually one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Regarding the claim limitation, wherein the leg cuff consists of only three cells, each cell consisting of a single compartment, Taheri teaches a leg cuff with three cells (B, C & D) wherein each cell consists of only one compartment (bladder).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., cells in the instant application are shown as single compartments in Figure 3 and it is clear from the language already in claim 1 that each cell wraps around the limb and so is at least as large as the circumference of the limb) are not recited in the rejected

claim(s). None of the claims require a cell size limitation nor do they require the cells being fully or completely wrapped around a limb. Thus, the cells disclosed by Taheri, which would at least partially wrap around a limb, meet the claimed cell limitations. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that "Barak, et al. does not suggest that it is possible to eliminate the thigh cuff and it certainly does not teach that doing so would make an effective device", applicant's attention is directed Barak's teaching in col. 10, lines 38-40, which clearly stated that "various changes, emissions to the form and detail thereof may be made therein" and thus omissions of the thigh cuff is possible, especially in view of the teaching of Taheri, as discussed above.

Applicant has not provided evidence that the Barak's device would not work effectively if the thigh cuff is eliminated. Moreover, it has been held that omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art. *In re Karlson, 136 USPQ 184.*

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the cells, when inflated, presents a smooth surface to the limb of the patient and apply an even compression to the limb) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicant's argument that Taheri is a device described as 'bad' by Barak, it is unclear what applicant relies upon for this assertion. First, from a close reading of Barak, there is no mention of the Taheri, Patent No. 4,624,244, or the use of the word "bad." Secondly, the prior art devices described by Barak are merely described as "big and use the conventional electrical outlets for the power supply" whereas the "compressor 66 taught by Taheri is a "small portable battery operated pump, and the electronics 70, 71, and 72 consist of a microcircuit which has very small volume and weight. The foregoing features thus enhance portability of the device." See: col. 4, lines 38-43.

Regarding applicant's argument that Taheri does not disclose a wearable controller, applicant is reminded that Taheri was used to teach a similar compression device having a sleeve with a leg cuff (27) and a foot cuff (11); the leg cuff consists of three cells: a gaiter cell (B) adapted to (partially) wrap around the lower limb in the region closest to the ankle, a mid-calf cell (C) adapted to (partially) wrap around the lower limb above the region occupied by the gaiter cell and an upper cell (D) adapted to (partially) wrap around the lower limb in the region between the mid-calf cell and the knee with each cell having only one compartment (bladders inside B, C, and D) for the treatment of diseased leg veins which result in venous hypertension; and although Taheri discloses a small portable pump and electronics, Barak was used to disclose a wearable controller.

Applicants' claims also recite that the leg cuff comprises three cells that wrap around the lower limb. Taheri does not disclose cells that wrap around the limb. From Taheri, it is clear that the cells (bladders) are restricted to covering the calf region of the leg in use (column 1, lines 50 and 51; column 2, lines 63 to column 3, line 3). The bladders in Taheri do not therefore wrap around the leg as required by instant claim 1.

In response to applicant's argument that Taheri does not disclose cells that wrap around the limb, none of the claims require a cell size limitation nor do they require the cells being fully or completely wrapped around a limb. Thus, the cells disclosed by Taheri, which would at least partially wrap around a limb, meet the claimed cell limitations. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant's argument that a physician **typically** will not treat a patient with a compression system which is **suitable for use in reduction of edemas, vascular disorders and the prevention of DEVT** because these disorders **generally** have an underlying chronic cause, such as heart failure or diabetes, which affects the whole body and these systems are isolated to a spot on the body has not been taken well. As disclosed by Barak, conventional compression devices are known for applying compressive pressure to a patient's limb. These types of devices are used to assist **in a large number of medical indications**, mainly the prevention of deep vein thrombosis (DVT), vascular disorders, reduction of edemas and the **healing of wounds**.

Moreover, Barak discloses his compression system will be suitable for use not only for severe cases of medical indication relating to the healing of wounds, reduction of edemas, vascular disorders and the prevention of DVT, but also to the mild cases, for whom, until now, the only alternate solution was the use of elastic stocking which are, clinically, inferior form of therapy compared with pneumatic compression systems. See. col. 1, lines 15-25 and col. 2, lines 42-49.

Thus, the combined references clearly teach the device as claimed and the incentive for modifying the device is to treat the portion of the leg in need of treatment, as determined by one having ordinary skill in the art, and since Taheri teaches a lower leg treatment devices consisting of a leg and a foot cuff, such a modification is clearly within the skill of the art.

***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771